Translation

PCT/MX2003/000054

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SOPH.PCT/002	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/MX2003/000054	International filing date (*day/month/year*) 10 July 2003 (10.07.2003)	Priority date (*day/month/year*)
International Patent Classification (IPC) or national classification and IPC A61K 31/5415, 9/08		
Applicant JIMENEZ BAYARDO, Arturo		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 06 February 2005 (06.02.2005)	Date of completion of this report 04 October 2005 (04.10.2005)
Name and mailing address of the IPEA/ES Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/MX2003/000054

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-7, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages 8-9, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-9	YES
	Claims		NO
Inventive step (IS)	Claims	1-5	YES
	Claims	6-9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations

The present application concerns a method for solubilising meloxicam which includes the following steps: prior mixing of ethyl alcohol and methilidene glycerol, incorporating meloxicam whilst alkalising the solution using sodium hydroxide until complete dissolution of the meloxicam, adding polysorbate 80 and agitating to achieve homogenisation. The meloxicam thus solubilised is mixed with a carrier solution, resulting in an ophthalmic solution that can be used to treat various ocular diseases

Reference is made to the following documents:

D1: US 2003055051 A 20.03.2003
D2: US 6284269 B 04.09.2001

Document D1 relates to an ophthalmic aqueous solution which is obtained by dissolving meloxicam (in concentrations of 0.01 - 6%) in an aqueous solution of trometamol together with other additives such as pH adjusters (in a sufficient quantity), surfactants (1%), viscosity regulators (1.3%), antioxidants, osmolarity regulators and preservatives (page 4 and examples 6-10).

Document D2 discloses an ophthalmic pharmaceutical

composition that contains meloxicam as the active ingredient together with agents which increase viscosity, surfactants and osmolarity regulators forming part of the carrier solution (columns 2 and 3).

The compositions disclosed in documents D1 and D2 differ from that claimed in claims 6 - 9 of the application only by the ranges of certain additional components included in the carrier solution. Since the use of those additional components is known in the prior art concerned with producing adequate conditions in the preparation of ophthalmic solutions, both from the point of view of their nature and of the proportion thereof in the composition, it is considered that said claims fail to involve an inventive step, since they result from a selection that is obvious to a person skilled in the art (PCT Article 33(3)).

Neither D1 nor D2 discloses a method for solubilising meloxicam using a mixture of ethyl alcohol and methilidene glycerol, alkalinisation of the solution and addition of polysorbate followed by homogenisation, such as claimed in claims 1 - 5 of the application. Those claims are therefore considered to meet the requirements for novelty, inventive step and industrial applicability pursuant to PCT Article 33(2), (3) and (4).

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Lack of clarity (PCT Article 6):

- the term "approximately" (claim 1) in relation to a range of values is vague and imprecise such that it is difficult to determine the exact scope of protection sought;

- the use of the trade name "Sophisen" in claims 5 and 6 of the application, without the application adequately describing the relationship between the components of the carrier solution, gives rise to a lack of clarity and leaves the reader in doubt as to the significance of the technical elements to which reference is made.